Amendments to the Drawings

In accordance with 37 CFR § 1.121(d)(1), attached hereto is one annotated sheet depicting changes made to the sole drawing figure. The attached figure has been amended to delete the "FIGURE 1" legend in accordance with 37 CFR § 1.84(u)(1).

Also attached hereto is one replacement sheet of drawings, incorporating the changes made to the sole figure, which replace the drawing figures originally submitted with the application.

Remarks

Reconsideration and allowance of this application, as amended, are respectfully requested.

The written description portion of the specification (including the title), the abstract of the disclosure, the drawing figure, and claims 1-13 have been amended. New claims 14-17 have been added. Claims 1-17 are now pending in the application. Claims 1, 14, and 15 are independent. The objection and rejection are respectfully submitted to be obviated in view of the amendments and remarks presented herein. No new matter has been introduced through the foregoing amendments.

The specification has been editorially amended for conformance with 37 CFR § 1.77(c), for consistency, and to correct any informalities. The abstract has been editorially amended for conformance with 37 CFR § 1.72(b). The sole drawing figure has been amended as described above in the "Amendments to the Drawings" section. The claims have been amended to more fully comply with U.S. practice. Entry of each of the amendments is respectfully requested.

Applicants' representative notes that a telephone inquiry was made to the examiner on December 20, 2006, with regard to a discrepancy that exists in the grounds of rejection presented at

Office Action pages 2 and 3[1]. During a telephone conference with Applicants' representative on December 22, 2006, the examiner acknowledged the discrepancy and indicated that the sole rejection in the Office Action is a combination rejection under 35 U.S.C. § 103(a).

35 U.S.C. § 103(a) - Polaschegg and Storey

Claims 1-13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,894,164 to Polaschegg in view of U.S. Patent No. 4,202,760 to Storey et al. (hereinafter "Storey").

With regard to Polaschegg, the Office Action asserts in pertinent part that Polaschegg discloses a blood treatment device with "a control unit 106 and an analysis unit 111," that "[t]he device comprise[s] at least one sensor 109 and a pump 114," and that "[t]he analysis unit is capable of determining the blood purification performance (col. 6, lines 26-38)." The Office Action acknowledges that "Polaschegg does not disclose the device differentiates between two materials namely sodium and one of potassium, glucose, creatinine, calcium, or phosphate."

The Office Action asserts that "Storey discloses removal of these substances in an apparatus and method for preparation of a

1 Immediately after the statement at Office Action page 3, numbered paragraph 4, of the § 103(a) rejection, the Office Action states that "[c]laims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Polaschegg USPN 4894164."

hemodialysis solution (col. 5, lines 1-62)." The Office Action concludes that "[i]t would have been obvious . . . to provide the invention of Polaschegg with the ability to monitor the blood purification of claimed materials for the benefit of returning to the patient blood with a normal concentration of the materials, which Storey teaches is desired (Storey col. 1, lines 45-50)."

The rejection of claims 1-13 under § 103(a) over Polaschegg and Storey is respectfully traversed. The combined disclosures of Polaschegg and Storey would not have rendered obvious Applicants' claimed invention.

As disclosed at specification page 10, line 18, through page 11, line 3, Applicants' invention is based on the following. Conventional hemodialyzers can determine the blood purification performance of the blood purification element (i.e., the dialysance of the dialyzer) in relation to a first material. For example, the sodium ion dialysance can be determined based on the change in its concentration relative to that in the fresh dialysis fluid.

However, it may also be necessary or desirable to determine the performance of the blood purification element in relation to a second material. See, e.g., Applicants' disclosure regarding the concentrations of potassium, calcium, and phosphate (specification page 23, line 33, through page 24, line 10).

Thus, an object of Applicants' device is "to determine the second blood purification performance, which is different from

the first blood purification performance, for a second material, without a further measurement method being necessary" (specification page 10, lines 18-22). Applicants' device is based on "relationships between the two blood purification performances which are stored in an analysis unit and which go beyond a mere identity assignment for identical blood purification performances as in the case of sodium ions and urea, [so that] the second blood purification performance may be determined directly" (specification page 10, lines 23-29).

Therefore, Applicants' claim 1 defines a device that includes in pertinent part:

> at least one sensor on at least one of the blood loop or dialysis fluid loop to detect and measure a concentration of a first material capable of penetrating the semipermeable membrane, and
> an analysis unit operatively connected to the at least one sensor to determine i) a blood purification performance L1 of the blood purification element for the first material based on the measurement values of the at least one sensor and ii) a blood purification performance L2 of the blood purification element for a second material, which is different from the blood purification performance L1 for the first material, based on the blood purification performance L1 for the first material.

The combined disclosures of Polaschegg and Storey do not teach all of Applicants' claim features. Neither Polaschegg nor Storey teaches an analysis unit that determines the blood purification performance L1 of the blood purification element, let alone according to Applicants' claimed invention.

As indicated above, the examiner asserts that Polaschegg discloses a device with "at least one sensor 109 and a pump 114," and that "[t]he analysis unit is capable of determining the blood purification performance (col. 6, lines 26-38)."

Contrary to the examiner's assertion, Polaschegg fails to disclose an analysis unit that is capable of determining the blood purification performance. First, Polaschegg's sensor 109 is located on the dialysis solution *inlet* line (see Polaschegg's Figure 1). A sensor located on the fresh dialysis solution line is not capable of determining blood purification performance in the blood purification element.

Second, in the disclosure relied upon by the examiner (i.e., "col. 6, lines 26-38"), Polaschegg discloses the following:

> The sensors 109 and 110 are connected to a monitoring device 111 by means of the signal line 122 and *in the case of a deviation of the dialysis solution from the set values* said monitoring device 111 gives an alarm and thereby controls the valves 112 and 113 via the signal line 123. Thus, on deviation of the values set the valve 112 is closed and the valve 113 of the bypass conduit 124 opened, *thus preventing dialysis solution of undesired composition or temperature reaching the dialyzer D*, the entrance of which is connected to the conduit 125 from the valve 112. The dialysis solution is accordingly delivered via the valve 113 directly to the pump 114 (emphasis added).

Thus, not only is Polaschegg's sensor 109 located on the dialysis solution *inlet* line, but it is used to prevent "dialysis solution of undesired composition or temperature reaching the dialyzer D." That is not Applicants' claimed invention.

Similarly, Storey is directed to an "Apparatus and Method for Preparation of a Hemodialysis Solution Optionally Containing Bicarbonate." The examiner relies upon Storey's disclosure at column 5, lines 1-62. But there, Storey summarizes his invention as follows: "The method of this invention, and the apparatus in loops 50 and 40, provide a spectrum of bicarbonate-acetate containing hemodialysis solutions ranging from no bicarbonate to no acetate" (column 5, lines 34-37). The examiner also relies upon Storey's disclosure at column 1, lines 45-50. There, Storey discloses that "[t]his invention provides a hemodialysis system which enables continuous formulation and supply to an artificial kidney of a hemodialysis solution, or dialysate, which contains the normally present sodium acetate component, or optionally may contain bicarbonate as a partial or total replacement therefor." Story, therefore, is directed to a sensor for freshly prepared dialysate, and fails to disclose Applicants' claimed device that is capable of determining the blood purification performance.

And, regardless of what Storey may disclose with regard to the composition of the dialysate (column 5, lines 1-62), the disclosure of Storey does not rectify the above-described deficiencies of Polaschegg.

Thus, Polaschegg and Storey each relate to a sensor for the freshly prepared dialysate. Neither reference describes how to evaluate the blood purification performance of the blood

purification element, for which it is necessary to analyze the fluid *leaving* the blood purification element. Thus, the combined disclosures of Polaschegg and Storey do not teach all of Applicants' claim features.

Furthermore, there is no teaching in either Polaschegg or Storey that would have led one to select the references and combine them in a way that would produce the invention defined by any of Applicants' pending claims. As indicated above, Polaschegg is directed to "preventing dialysis solution of undesired composition or temperature reaching the dialyzer D." Storey is directed to preparation of a hemodialysis solution optionally containing bicarbonate. There is simply no teaching in either Polaschegg or Storey that would have led one to select the references and combine them, let alone in a way that would produce Applicants' claimed invention.

For at least the above reasons, reconsideration and withdrawal of the rejection of claims 1-13 under § 103(a) based on Polaschegg and Storey are respectfully requested.

New claims 14-17 have been added to further define the scope of protection sought for Applicants' invention. New claims 14-17 are also allowable. Since each of independent claims 14 and 15 includes at least the features discussed above with respect to the applied prior art references, neither Polaschegg nor Storey

either anticipates or would have rendered obvious the device defined by any of new claims 14-17.

In view of the foregoing, this application is now in condition for allowance. If the examiner believes that an interview might expedite prosecution, the examiner is invited to contact the undersigned.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: John C. Holman Reg. No. 34,378
Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N. W.
Washington, D.C. 20004
Telephone: (202) 638-6666
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Annotated Sheet Showing Changes